

REMARKS

The Final Office Action dated April 30, 2007 ("Office Action") has been received and noted. Claims 1, 3-5 and 30 were examined. Claims 1, 3-5 and 30 were rejected. Claims 1, 3-5 and 30 are amended. Support for the amendments can be found in, for example, Examples 1-14 and Figure 5C of the Application. As such, no new matter has been added. Applicants respectfully request reconsideration of the claims in view of the above-amendments and the following remarks.

A telephone call was placed to the Examiner by the attorney of record on September 22, 2007 regarding the objection to the specification on page 2, paragraph 6 of the Office Action. The attorney of record was unable to locate the specific sequence to which the Examiner objected; the attorney of Record was referring the specification filed on July 19, 2004. The Examiner returned the telephone call on September 24, 2007 and stated that the sequence was located on the certified English translation of the Korean application No.: 10-2002-0003184 filed on September 21, 2006, and specifically stated that the sequence was "YGKKKRRQRRR."

I. Sequence Compliance

The specification is objected to for failure to comply with the sequence guidelines. Appropriate correction has been made in the above amendment. Applicants respectfully request withdrawal of the objection.

II. Claims Rejected Under 35 U.S.C. § 101

Claims 1, 3-4 and 30 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter according to the Examiner. Independent claim 1 has been amended to recite, "[a] peptide wherein the peptide is a purified peptide having SEQ. ID NO.:1" and independent claim 5 has been amended to recite, "preparing a peptide construct wherein the peptide construct consists of a purified peptide having SEQ. ID NO.:1." (App., claims 1, 5.) The newly amended claims use "closed" terminology and also recite that the peptides are "purified."

In view thereof, Applicants believe that the newly amended claims do not encompass a product of nature, as stated by the Examiner. (Office Action, p.3.)

Moreover, Applicants respectfully submit that *Narayanan* is not enabled with respect to amended independent claims 1, 5 and 30. *Narayanan* describes methods of detecting cancer in a biological sample by detecting SIM2 nucleic acid or protein in the sample and methods for treating cancer and identifying compounds that modulate SIM2 expression. (*Narayanan*, Abstrac.t) Among the sequences disclosed in *Narayanan* is SEQ. ID NO.:3 which is the native form of the human transcription factor SIM2 gene and contains 667 amino acid residues. (*Narayanan*, col. 39-43.) SEQ. ID NO.:3 is simply a repeat of U80456 of GenBank. (see GenBank U80456 available at <http://www.ncbi.nlm.nih.gov/Genbank/GenbankSearch.html>) *Narayanan* is not enabled with respect to SEQ. ID NO.:1 of claims 1, 5 and 30 because *Narayanan* does not enable one skilled in the art to make and use the claimed invention. There is no indication that *Narayanan* specifically identifies SEQ. ID NO.:1 or any of its newly discovered capabilities, as discovered by Applicants and claimed in the Application. *Narayanan* does not give any working examples of SEQ. ID NO.:1 and is void in direction or guidance with respect to how to make and use SEQ. ID NO.:1. Moreover, if every newly discovered peptide, protein or nucleic acid sequence encoding a newly discovered peptide or protein derived from a known nucleic acid sequence precluded patentability, then no patent would issue for sequences, including the sequences disclosed in *Narayanan*. Dependent claims 3 and 4 depend on independent claim 1 and therefore include all of the limitations thereof. Accordingly, Applicants respectfully submit that the claims are in condition for allowance.

III. Claims Rejected Under 35 U.S.C. § 112, first paragraph

Claims 1, 3-5 and 30 were rejected under 35 U.S.C. § 112, first paragraph for, according to the Examiner, failing to meet the enablement requirement. Applicants respectfully submit that the claims rejected under 35 U.S.C. § 112, first paragraph are enabled for the reasons set forth in section II of this Response and are in condition for allowance.

IV. Claims Rejected Under 35 U.S.C. § 112, second paragraph

Claims 4 and 30 were rejected under 35 U.S.C. § 112, second paragraph for being incomplete for omitting essential elements according to the Examiner. Dependent claim 4 has been amended to recite, “[t]he peptide of claim 1, wherein a resulting fusion protein consisting of the peptide and the biologically active, functional and/or regulatory molecule is capable of being administered *in vivo* . . .” and independent claim 5 has been amended to recite, “[a] method of facilitating the transduction of a biologically active, functional or/and regulatory molecule into a prokaryotic or eukaryotic cell comprising . . . delivering the peptide construct *in vivo* to a subject through administration routes comprising intramascular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhalation routes.” (App., claims 4, 30.) Representatively, Example 5 of the Application states that the transduction of a desired protein using Sim-2 is “administered by intraperitoneal injection” to mice. (App., Ex. 5, ¶ [0088].) A subsequent FACS analysis was carried out on isolated splenocyte cells to monitor the eGFP that was transduced into the cells. (App., ¶ [0088].) Figure 5B illustrates that the desired protein, i.e., β-gal, was transduced efficiently to the isolated splenocyte cells. (*Id.*) In view of the above amendments/remarks, Applicants respectfully submit that the are in condition for allowance.

V. Claims Rejected Under 35 U.S.C. § 102

Claims 1, 3-5 and 30 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,780,642 to Narayanan et al. (“*Narayanan*”). A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131. Applicants respectfully submit that each and every element in amended claim 1 and its respective dependent claim is not set forth in the cited references.

Amended independent claim 1 recites “[a] peptide wherein the peptide is a purified peptide having SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2, wherein the peptide is capable of transducing a biologically active,

functional or/and regulatory molecule into prokaryotic cells or eukaryotic cells.” Amended independent claim 5 recites,

A method of facilitating the transduction of a biologically active, functional or/and regulatory molecule into a prokaryotic or eukaryotic cell comprising:

preparing a peptide construct wherein the peptide construct consists of a purified peptide having SEQ. ID NO.:1 derived from human transcription factor SIM2 beginning at the 558th marker of human transcription factor SIM2 and ending at the 566th marker of human transcription factor SIM2 and a biologically active, functional or/and regulatory molecule; and

delivering the peptide construct *in vivo* to a subject through administration routes comprising intramuscular, intraperitoneal, intravein, oral, nasal, subcutaneous, intradermal, mucosal and inhalation routes.

(App., claims 1, 5.) The newly amended claims use “closed” terminology and also recite that the peptides are “purified.” As a result, the claimed peptide having SEQ. ID NO.:1 does not read on any protein comprising the 9 amino acid sequence AKARQAAR, as stated by the Examiner. (Office Action, p.6.) Dependent claims 2-4 depend on independent claim 1 and therefore include all of the limitations thereof. Accordingly, Applicants respectfully submit that the claims rejected under 35 U.S.C. § 102(e) are in condition for allowance.


CONCLUSION

In view of the foregoing, it is believed that all claims now pending and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 500-4787.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web to the United States Patent and Trademark Office on October 1, 2007.



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